IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA

IN RE:)	
CAMP LEJEUNE WATER LITIGATION)	Case No: 7:23-cv-897
)	
)	UNITED STATES' RESPONSE
This Document Relates To:)	TO PLAINTIFFS' APPEAL OF ORDER
ALL CASES)	DENYING MOTION TO COMPEL

Magistrate Judge Jones properly denied Plaintiffs' Motion to Compel, concluding that "the public interest in both maintaining the integrity of [the Agency for Toxic Substances and Disease Registry's ("ATSDR")] peer review procedure and avoiding the damage resulting from premature release of any draft [Cancer Incidence Study ("CIS")] outweighs Plaintiffs' need." D.E. 85 ("Order"), at 11. The Order is grounded in the law and is based on thorough consideration of the Declaration of the Director of ATSDR, Dr. Aaron Bernstein, and the accompanying Privilege Log. D.E. 74-1, Bernstein Decl.; D.E. 74-2, Privilege Log. The Order was not clearly erroneous or contrary to law, and Plaintiffs have failed to raise any arguments that warrant reversal of the Order. See Fed. R. Civ. P. 72(a); Local Civ. R. 72.4(a)(4). Judge Jones' decision that the Declaration and Privilege Log were sufficient to determine the applicability of the privilege is in line with the controlling law that a privilege log "is a surrogate for the production of documents for in camera review[.]" Ethyl Corp. v. EPA, 25 F.3d 1241, 1249 (4th Cir. 1994). Moreover, Judge Jones' analysis of the balancing factors is supported by the entirety of the record. Judge Jones recognized the chilling effect disclosure of the draft CIS would have on the peer review process and potential "public confusion that might result from premature release of [] nonbinding deliberations." D.E. 85, at 10. Accordingly, the United States respectfully requests that the Court affirm the Order and uphold the application of the deliberative process privilege to ATSDR's draft CIS and related materials while the draft CIS undergoes statutorily mandated review.

PROCEDURAL BACKGROUND

This discovery dispute arises from Plaintiffs' Second Request for Production ("RFP"), which included a broad request for "any past, current, draft, planned or future study or report (including any supporting data), whether completed or uncompleted, published or unpublished, approved for dissemination or not, . . . performed by: (1) a United States governmental entity including but not limited too [sic] ATSDR" D.E. 74-3, at 7 (Pls.' Second RFP). The United

States served its Responses to the Plaintiffs' Second RFP asserting the deliberative process privilege over all drafts of the CIS and related materials as it undergoes the review process. D.E. 74-4, at 3–4 (United States' Resp. to Pls.' Second RFP). Plaintiffs then filed a Motion to Compel production of the Draft CIS. The issue was fully briefed before Judge Jones, pursuant to Local Civ. R. 7.1. Thereafter, Judge Jones issued the Order denying the Motion to Compel, which thoroughly considered the Parties' arguments as well as the Declaration and Privilege Log.

ARGUMENT

Judge Jones correctly held that the draft CIS and related materials are protected by the deliberative process privilege, as supported by the Declaration of ATSDR Director Dr. Bernstein and the Privilege Log. *See Pittman v. U.S.*, 878 F. Supp. 833, 836 (E.D.N.C. 1994) ("detailed affidavits may be used to satisfy the agency's burden of justifying the application of the privilege").

I. Judge Jones Properly Concluded that the Draft CIS and Related Materials are Protected from Disclosure by the Deliberative Process Privilege.

Judge Jones' Order is firmly rooted in the law and supported by the evidence. As Judge Jones recognized, Congress established ATSDR under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), in part, to "establish and maintain inventory of literature, research, and studies on the health effects of toxic substances[.]" D.E. 85, at 6 (citing 42 U.S.C. § 9604(i)(1)(B)). CERCLA mandates that these studies "shall be reported or adopted *only after appropriate peer review." Id.* (emphasis added).¹ Judge Jones concluded that the draft CIS and related materials are deliberative because "only after clearing these multiple reviews—and receiving 'approval' from ATSDR and CDC—may the CIS join the 'inventory of literature, research, and studies' kept by the agency." *Id.* at 6. Judge Jones applied the same logic to the analytical data files, stating that "[d]ata files containing 'analyses' which 'reveal the

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¹ This Congressional-mandated peer review process is separate and distinct from any peer review that may be subsequently necessary for publication in an independent scientific journal.

agency's deliberations' regarding the final scientific opinions and conclusions in the CIS are deliberative." *Id.* at 7.

Second, Judge Jones determined that the draft CIS and related materials were predecisional because "there is no dispute that the CIS has not been added to ATSDR's 'inventory of [scientific] literature." *Id.* at 7. As Judge Jones explained, Dr. Bernstein's Declaration describing the status of the CIS in the CERCLA review process demonstrates that the draft CIS is currently undergoing review and that its content may substantially change. *Id.* As such, "it does not reflect a final agency decision so both it and the related materials are predecisional." *Id.* at 8.

Judge Jones also applied the relevant balancing factors in holding that "the public interest in both maintaining the integrity of ATSDR's peer review procedure and avoiding the damage resulting from premature release of any draft CIS outweighs Plaintiffs' need." *Id.* at 11. Judge Jones explained that "the chilling effect of disclosure" weighed heavily in favor of the United States' position to protect the draft study from disclosure while it remains in the peer review process. *Id.* at 9. Moreover, Judge Jones concluded "there is risk that compelling production of an incomplete CIS subject to change would garner significant attention and result in 'public confusion,' as well as 'undermine the public's trust in and credibility of ATSDR's scientific products." *Id.* at 10–11 (quoting D.E. 74-1, Bernstein Decl.).

II. Judge Jones' Order was not Clearly Erroneous or Contrary to Law.

Under Local Civ. R. 72.4(a), Judge Jones' Order should not be set aside unless it is "clearly erroneous or contrary to law." Plaintiffs cannot meet this standard.

Under this standard, "[a] finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." . . . If the magistrate judge's account of the evidence is plausible in light of the record viewed in its entirety, the reviewing court may not reverse it even though had it been sitting as the trier of fact, it would have weighed the evidence differently.

U.S. v. Coyle, No. 13-HC-2096, 2013 WL 5519602, at *1 (E.D.N.C. Sept. 19, 2013).

a. Judge Jones Correctly Determined that the Draft CIS and Related Materials are Protected under the Deliberative Process Privilege.

Judge Jones correctly determined that the draft CIS and related materials are protected from disclosure by the deliberative process privilege because the information is both predecisional and deliberative. Predecisional materials are those "prepared in order to assist an agency decisionmaker in arriving at his decision." *Heyer v. U.S. Bureau of Prisons*, No. 11-CT-03118, 2014 WL 4545946, at *3 (E.D.N.C. Sept. 12, 2014). Deliberative material "reflects the give-and-take of the consultative process" and may reveal the decision process. *City of Virginia Beach v. U.S. Dep't of Comm.*, 995 F.2d 1247, 1253 (4th Cir. 1993) (citations omitted). The privilege "encourages free-ranging discussion of alternatives; prevents public confusion that might result from the premature release of such nonbinding deliberations; and insulates against the chilling effect likely were officials to be judged not on the basis of their final decisions, but for matters they considered before making up their minds." *Id.* at 1252–53 (quotation omitted).

As Judge Jones explained, the draft CIS is deliberative because whether the draft CIS should be published "is the statutory prerogative of ATSDR." D.E. 85, at 6. Federal law mandates that the CIS "shall be reported or adopted only after appropriate peer review." 42 U.S.C. §§ 9604(i)(1)(B); (i)(13). The draft CIS and related materials were prepared to help ATSDR formulate its decision as to the form and content of the final study and, thus, those materials are deliberative. See U.S Fish & Wildlife Serv. v. Sierra Club, Inc., 592 U.S. 261, 267 (2021).

Courts have found that peer review materials related to scientific studies are predecisional because they "preceded the agency's decision whether to and in what form to publish the Report." *Formaldehyde Inst. v. U.S. H.H.S.*, 889 F.2d 1118, 1124 (D.C. Cir. 1989); *see also Hooker v. U.S. H.H.S.*, 887 F. Supp. 2d 40, 57 (D.D.C. 2012), *aff'd*, No. 13-5280, 2014 WL 3014213 (D.C. Cir. May 13, 2014) (collecting cases); *accord Virginia Beach*, 995 F.2d at 1253 (holding that an agency

is not required to "identify a specific decision in connection with which a memorandum is prepared" for the privilege to apply). As ATSDR's Director explained, the draft CIS is currently undergoing a mandatory peer review process. D.E. 74-1. Consequently, the draft CIS "does not reflect a final agency decision so both it and related materials are predecisional." D.E. 85, at 8.

Moreover, it is "indisputable" that the disclosure of the draft CIS and peer review materials would "seriously harm the deliberative process." *See Formaldehyde Inst.*, 889 F.2d at 1118. In similar circumstances, the D.C. Circuit recognized the importance of protecting such draft studies from disclosure, because otherwise "Government employees who must publish as part of their job responsibilities would no longer receive the candid, constructive advice that contributes to the author's efforts to produce the best product possible." *Id.* Here, premature disclosure of an unfinished scientific study, the peer review comments, and the underlying analytical data would likewise hinder the work of the study authors and risk the integrity of ATSDR's processes. Therefore, the Court should uphold Judge Jones' protection of the draft CIS and related materials from disclosure under the deliberative process privilege.

b. Judge Jones' Application of the Deliberative Process Privilege Based on Consideration of the Bernstein Declaration and Privilege Log was Not Clearly Erroneous or Contrary to Law.

Plaintiffs' criticisms of Judge Jones' decision are unfounded. Plaintiffs take issue with Judge Jones' review of the Declaration and the accompanying Privilege Log without an *in camera* review. Judge Jones' decision that the Declaration and Privilege Log were sufficient to rule on the privilege is in line with controlling law. As the Fourth Circuit explained in *Ethyl Corp. v. EPA*, 25 F.3d at 1249, a privilege log² "is a surrogate for the production of documents for *in camera* review,

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² As in *Ethyl Corp.*, privilege logs are often referred to as a *Vaughn* Index after *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973), in the context of Exemption 5 to the Freedom of Information Act ("FOIA"). The Supreme Court and Judge Jones have recognized cases applying Exemption 5 of FOIA are informative to the assertion of deliberative process privilege. *See Sierra Club, Inc.*, 141 S. Ct. at 785; D.E. 85, at 4 n. 1.

designed to enable the district court to rule on a privilege without having to review the document itself." The court in *Ethyl* noted that "[w]hile an *in camera* review was recognized to be available as a possible method of reviewing an agency decision, . . . such a process can be cumbersome and overburdening for the judiciary." *Id.* Only where the privilege log is "so vague as to leave the district court with an inability to rule, then some other means of review must be undertaken, such as *in camera* review." *Id.* 3

Judge Jones was well within his discretion to determine the applicability of the deliberative process privilege based upon Declaration and the detailed Privilege Log, without an *in camera* review. The Privilege Log provides the date, document type, source, a description of the category, justification for asserting the privilege, and the number of files being withheld by category. D.E. 74-2. Additionally, Dr. Bernstein, who personally reviewed the materials, describes in his Declaration the necessity for protecting draft studies and related materials based on the statutorily mandated review process, which governs ATSDR's decision to add studies to their inventory. D.E. 74-1. As demonstrated by the Order's numerous references to the Declaration and Privilege Log, those materials provided Judge Jones with an adequate basis to determine the deliberative process privilege applied to the draft CIS and materials identified on the Privilege Log. Based on his thorough analysis, Judge Jones concluded (1) "[a]ll the documents identified by Defendant are deliberative; they are 'prepared to help the agency formulate its position,' specifically, to publish

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³ District Courts within the Fourth Circuit agree. *See Worsham v. U.S. Dep't of the Treasury*, No. ELH-12-26352013, WL 5274358, at *13 (D. Md. Sept. 17, 2013) ("[I]n camera inspection is not necessary in every case."); *Christian Coal Int'l v. United States*, No. 2:01CV377, 2002 WL 1482523, at *2 (E.D. Va. May 31, 2002) ("[T]he Court in its discretion may order an *in camera* review of the documents to determine the applicability of the claimed privilege, but it need not do so.").

a hypothetical final CIS;" and (2) "the documents are all 'predecisional'; there is no dispute that the CIS has not been added to ATSDR's 'inventory of [scientific] literature." D.E. 85, at 6–7.

Moreover, contrary to Plaintiffs' argument, Judge Jones remained within his discretion in determining the entirety of the materials identified were privileged, rather than applying the privilege to certain parts of the CIS or parts of the related materials. Plaintiffs provide no basis to conclude that certain parts of a draft scientific study can be segregated from the deliberative and predecisional portions. Indeed, changes to the draft CIS, when compared to the forthcoming published study, would unquestionably reveal the decision-making process of ATSDR.

Additionally, as Judge Jones concluded, the entirety of the analytical datasets are not simply data lists but contain the "analyses' which 'reveal the agency's deliberations' regarding the final scientific opinions and conclusions in the CIS." D.E. 85, at 7. Similarly, this Court has stated, "[b]ecause the list sought here is composed of selective fact, it is possible that the list could reveal the deliberative process." *Farmworkers Legal Servs. of N.C., Inc. v. U.S. Dep't of Lab.*, 639 F. Supp. 1368, 1373 (E.D.N.C. 1986). As such, Judge Jones did not commit clear error in determining that the entirety of the underlying analytical data remains protected under the deliberative process privilege.

Now, for the first time on appeal, Plaintiffs have requested in camera review and critiqued

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⁴ Without any basis and for the first time on appeal, Plaintiffs accuse the United States of acting in bad faith. D.E. 101, at 5–6. This is not true. The United States' formal assertion of the deliberative process privilege through the Declaration and Privilege Log demonstrate the effort taken by the United States to withhold only documents that are justifiably privileged. Plaintiffs offer nothing to support their allegation that "the government unfortunately has a track record of hiding critical information from its veterans regarding contamination at Camp Lejeune." *Id.* Without any support to justify such statement, Plaintiffs cite to *Rein v. U.S. Patent & Trademark Office*, 553 F.3d 353, 356 (4th Cir. 2009) – a patent case regarding Blackberry Wireless telephone and e-mail devices – for the proposition that specificity is required in the privilege log. The case does not support Plaintiffs' accusation of bad faith related to Camp Lejeune as it does not involve Camp Lejeune, veterans, or ATSDR. In fact, the court in *Rein* refused to tolerate the plaintiff's allegation of bad faith where the plaintiff "offers no support for this proposition, nor any evidence of bad faith on the part of the Agencies." *Id.* at 374. The Court here has asked Parties to act cooperatively. D.E. 23. Such serious, baseless allegations should not be baldly asserted without any substantiation.

the content of the Declaration and Privilege Log. A party cannot hold back arguments before the Magistrate in the hopes of raising new arguments on appeal. *Callas v. Trane CAC, Inc.*, 776 F. Supp. 1117, 1119 (W.D. Va. 1990), *aff'd*, 940 F.2d 651 (4th Cir. 1991). Plaintiffs made the strategic decision to file a motion to compel, despite the United States' promise that a privilege log and declaration were forthcoming. D.E. 74-4, at 3-4 (United States' Resp. to Pls.' Second RFP). In addition, Plaintiffs failed to seek *in camera* review or raise issues regarding the Declaration and Privilege Log before the Order. Plaintiffs cannot belatedly seek *in camera* review and raise these issues when they were never raised before Judge Jones. This course of action would defeat the purpose of this Court appointing Judge Jones to oversee discovery matters if the District Court were required to review new arguments that could have been raised before Judge Jones or remedied through a conference with counsel. Accordingly, the arguments before the Magistrate Judge should constitute the entirety of the arguments on appeal and the Plaintiffs' arguments regarding *in camera* review, the Declaration, and the Privilege Log should be deemed waived.

Even if not waived, Plaintiffs' arguments must fail. The Privilege Log describes six categories of information protected by the deliberative process privilege and provides justification for the privilege. This provided Plaintiffs with enough information to "assess the claim." Fed. R. Civ. P. 26(b)(5)(A)(ii); see also Ethyl Corp., 25 F.3d at 1250 (the purpose of the privilege log and declaration is to provide the Court with sufficient information to determine the applicability of the privilege). Further, Dr. Bernstein's Declaration, his personal review of the documents, and the citation to federal regulations requiring the peer review process provide further context and justification for the claim. The Privilege Log details precise justifications. Any repetition in the Privilege Log is a result of the fact that the materials are intertwined with a single study that is currently undergoing the statutorily mandated peer review process, and the documents are withheld

in response to a single discovery request served by Plaintiffs. In tandem, the Declaration and Privilege Log provided Judge Jones with the information necessary and legally sufficient to uphold the United States' assertion of privilege.

Plaintiffs' arguments ignore the realities of the litigation. The Stipulated Order Establishing Protocol for Document Collection and Production, D.E. 52, jointly negotiated and entered by the Court, provides "[t]he parties agree that alternatives to document-by-document privilege and confidentiality logs presumptively meet the requirements of Rule 26(b)(5)(A)." Had Plaintiffs waited to see the log before filing the motion to compel, they could have asked for a meet and confer and raised questions about the entries. Since production of the Declaration and Privilege Log, Plaintiffs have not raised their concerns directly with the United States nor asked for a meet and confer. Instead, Plaintiffs chose to raise these concerns for the first time in this appeal.

c. Judge Jones' Analysis of the Balancing Factors was Not Clearly Erroneous or Contrary to Law.

After correctly concluding that the draft CIS and related materials are protected under the deliberative process privilege, Judge Jones further held that the public interest weighed in favor of upholding the privilege. The Order considered each of the four balancing factors: "(1) the relevance of the evidence to the lawsuit; (2) the availability of alternative evidence on the same matters; (3) the government's role (if any) in the litigation, and (4) the extent to which disclosure would hinder frank and independent discussion regarding contemplated policies and decisions." D.E. 85, at 8–11 (citing *Trump v. Stone*, 453 F. Supp. 3d 758, 766 (D. Md. 2020)).

Plaintiffs argue that Judge Jones' Order failed to acknowledge the importance of the draft CIS to Plaintiffs' claims. This is incorrect. Judge Jones stated, "[q]uery what evidentiary weight the court would give to a non-final CIS." D.E. 85, at 9. Thus, Judge Jones was evaluating the appropriate evidentiary weight of the CIS in non-final versus final form and acknowledging that

the weight would be greater once ATSDR could publish a final CIS that had been thoroughly vetted by the peer review process. Judge Jones also found that the integrity of the CIS and peer review process would be placed at risk if premature disclosure was required. *Id.* Dr. Bernstein confirmed in his declaration that release of a draft study would "suppress the routine scientific review process and have a chilling effect on deliberations." D.E. 74-1. The assertion of privilege over these materials ensures that the scientific process can continue as mandated and not be conducted within the confines of a fishbowl. *Virginia Beach*, 995 F.2d at 1252. The Order recognized the importance of a final study and though Plaintiffs choose to ignore the scientific process, such choice does not transform the Court's decision into error.

Additionally, the Order correctly determined that alternative evidence exists. ATSDR has published numerous studies regarding Camp Lejeune, many of which include analysis of cancers. Similarly, other literature exists on the relationship between relevant chemicals and cancer. Despite Plaintiffs' lamentations, nothing in the Order prevents individuals from reviewing the published literature and filing a claim under the Camp Lejeune Justice Act alleging an injury.

The interest of the public is best served by the publication of a complete and final scientific study. Judge Jones notes "apprehension is warranted here" regarding premature publication of the CIS and any related materials given the volume of the litigation and a news article reporting on the existence of the draft CIS. D.E. 85, at 10. As Judge Jones aptly explained, "compelling production of an incomplete CIS subject to change would garner significant attention and result in 'public confusion,' as well as 'undermine the public's trust in and credibility of ATSDR's scientific products." *Id.* at 10–11. Accordingly, any potential damage does not justify premature release of the draft CIS and related materials.

CONCLUSION

For the foregoing reasons, Plaintiffs' appeal of the Order should be denied.

Dated: January 16, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 16, 2024, a copy of the foregoing document was served on all counsel of record by operation of the court's electronic filing system and can be accessed through that system.

<u>/s/ Elizabeth K. Platt</u> ELIZABETH K. PLATT